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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/316,935 | 05/22/1999 | CORNELIS J.M. MELIEF | 98-4 | 8495 |

26839 7590 04/17/2002

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| EXAMINER |
|---|
| BECKERLEG, ANNE M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | 19 |

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

| Application No. | Applicant(s) |
|---|---|
| 09/316,935 | Melief et al. |
| **Examiner** | **Art Unit** |
| Anne Marie Beckerleg | 1632 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED *Mar 12, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *5* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
*see attached comments.*

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: *none*

   Claim(s) objected to: *none*

   Claim(s) rejected: *14-19*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

11. ☐ Other:

A.M.S. BECKERLEG
PATENT EXAMINER

Applicant's proposed after-final amendments cancel all the previously pending claims and add new claims 14-19. The pending rejection of claims 1-7 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained over newly proposed claims 14-19. Please note that claims 14-16 are included in the this rejection based on "how to use" these compositions according to the intended use identified in the specification, i.e. use as a pharmaceutical composition for the treatment of cancer or disease in vivo. Applicant's arguments have not been found persuasive in overcoming these grounds of rejection for reasons of record as discussed in detail in paper no. 16. Briefly, the applicant argues that the specification and the prior art teaches the characteristics of peptides which bind to MHC class I. The office has previously acknowledged that peptides which bind to MHC class I and stimulate CTL were known at the time of filing. However, as discussed in detail in the previous office action, the specification fails to provide sufficient guidance as to the physical or biological characteristics of peptides other than the E7 peptide having the sequence of SEQ ID NO:3 which are capable of having a therapeutic effect on any disease when administered *in vivo* in combination with an anti-CD40 antibody. In regards to applicant's arguments that it was commonly known that CTL-mediated immunity plays a major role in eliminating cells that are infected with pathogenic agents and that as such an increase in CTL will result in improved clearance of infectious agents, the previous office action specifically cited the teachings of Yasutomi et al. which demonstrate that the generation of CTL against SIV peptides fails to result in any therapeutic response against SIV infection.